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12	UNITED STATES DISTRICT COURT	
13	NORTHERN DISTRICT OF CALIFORNIA	
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15	AIDS HEALTHCARE FOUNDATION, INC.,	Case No. 3:16-cv-00443-WHA
16	Plaintiff,	
17	v. GILEAD SCIENCES, INC.; JAPAN	DEFENDANT EMORY UNIVERSITY'S NOTICE OF MOTION AND MOTION TO DISMISS
18 19	TOBACCO, INC.; JAPAN TOBACCO INTERNATIONAL U.S.A., INC.; and EMORY UNIVERSITY,	Hearing Date: April 28, 2016 Hearing Time: 8 AM
20	Defendants.	Dept: Courtroom 8 – 19 <sup>th</sup> Floor Judge: Honorable William Alsup
21	Defendants.	Juage. Honorable william Ausup
22		Complaint Filed: January 26, 2016
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#### **NOTICE OF MOTION AND MOTION TO DISMISS**

PLEASE TAKE NOTICE that on March 21, 2016, Defendant Emory University hereby moves to dismiss all claims asserted against it pursuant to Federal Rule of Civil Procedure 12(b)(6). In accordance with Paragraph 6 of the Supplemental Order issued by the Court, Emory University respectfully requests that a hearing be set for Thursday, April 28, 2016 at 8 AM before the Honorable William Alsup of the United States District Court for the Northern District of California, San Francisco Division, located at 450 Golden Gate Avenue, San Francisco, CA. Emory University's motion is made under the auspices of Rule 12(b)(6) of the Federal Rules of Civil Procedure and is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the Complaint filed in this matter, and upon such other matters as may be presented to the Court at the time of the hearing or otherwise.

#### STATEMENT OF ISSUES TO BE DECIDED

- 1. Whether the plaintiff, AIDS Healthcare Foundation, Inc., has failed to state a viable claim under Section 1 of the Sherman Antitrust Act against Emory University, given the lack of substantive factual allegations concerning Emory University and its alleged license with Defendant Gilead Sciences, Inc. ("Gilead"), thus requiring dismissal of Count III under Federal Rule of Civil Procedure 12(b)(6).
- 2. Whether the plaintiff has standing to assert a cause of action under Section 1 of the Sherman Act despite its acknowledgment that it does not purchase the disputed product directly from any of the antitrust defendants, thus requiring dismissal of Count III under Federal Rule of Civil Procedure 12(b)(6).

#### MEMORANDUM OF POINTS AND AUTHORITIES

#### I. INTRODUCTION

Plaintiff AIDS Healthcare Foundation, Inc. accuses Defendants Emory University, Japan Tobacco International U.S.A., Inc., and Japan Tobacco Inc. of conspiring to prevent competition with Gilead's most recent HIV drug, Genvoya, in violation of Section 1 of the Sherman Antitrust Act. The claim, as it relates to Emory University, is premised on nothing more than the

existence of a licensing agreement between Emory University and Gilead relating to one of the compounds included in the final formulation of Genvoya. Indeed, the thirty-three page Complaint references Emory University only six times, with the primary allegations made "on information and belief" alone. Even assuming the AIDS Healthcare Foundation's unsubstantiated allegations to be true, such exclusive licenses are presumptively legal under antitrust law and cannot serve as the sole predicate for a cause of action under Section 1 of the Sherman Antitrust Act. Without plausible factual corroboration, the plaintiff's conclusory allegations in the Complaint do not satisfy the required pleading standard. Accordingly, the Court should dismiss Count III of the Complaint with respect to Emory University and dismiss 

#### II. FACTUAL ALLEGATIONS

Emory University from this case.

In November of 2015, Gilead released Genvoya, a lifesaving treatment for those infected with HIV. *See* Compl. ¶ 9. One component of Genvoya is tenofovir alafenamide (TAF), which the plaintiff describes as a patented "prodrug" of the compound Tenofovir. *See id.* ¶ 1. The plaintiff alleges that patents claiming TAF are potentially invalid. *Id.* ¶ 5. Thus, according to the Complaint, Gilead chose to combine TAF with other antiretroviral agents protected by "comparatively stronger" patents. *Id.* ¶¶ 7-8. As a result, the plaintiff argues that Gilead will be able to maintain a monopoly status in the market for products that contain TAF. *Id.* ¶ 90.

Emory University developed emtricitabine, one of the agents with which Gilead combined TAF. The plaintiff contends, on information and belief, that Emory University entered into an "exclusive licensing agreement for patents relating to emtricitabine" with Gilead and that Emory University received \$525 million in consideration for the license. *See id.* ¶ 123. The plaintiff then concludes, again on information and belief, that Emory University "knew or should have known" that its compound was "to be used in a conspiracy to reap monopoly profits on tenofovir." *Id.* § 126. Based on this license alone, the Complaint alleges that Emory University "entered into an agreement and conspiracy with Gilead . . . with the knowledge and intent that Gilead would use those patents to erect barriers to entry that would create and maintain

unjustified monopoly profits in the sale of TAF," and that Emory University would receive

"substantial payments" for participating in the conspiracy. *Id.* ¶ 127. Other than the existence of

a license agreement, the Complaint contains no substantive allegations regarding Emory

University, the specifics of the alleged license with Gilead, or the purported conspiracy among

Gilead, Emory University, and other entities. In particular, there is no allegation that Emory

University played any role in developing, marketing, selling, or distributing Gilead's Genvoya

product or any other TAF-containing product, which are the focus of the plaintiff's allegations.

#### III. ARGUMENT

## A. The Complaint Fails To State A Claim Against Emory University Upon Which Relief Can Be Granted

The sole cause of action asserted against Emory University arises under Section 1 of the Sherman Antitrust Act. *See id.* ¶¶ 123-33. Section 1 renders illegal "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations." 15 U.S.C. § 1. Bare assertions of conspiracy, however, are insufficient. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). The pleadings must allege sufficient "factual matter (taken as true) to suggest that an [illegal] agreement was made . . . [and] to raise a reasonable expectation that that discovery will reveal evidence of illegal agreement." *Id.* Thus, "[t]o state a claim under Section 1 . . . claimants must plead not just ultimate facts (such as a conspiracy), but evidentiary facts which, if true, will prove: (1) a contract, combination or conspiracy among two or more persons or distinct business entities; (2)

<sup>&</sup>lt;sup>1</sup> The dearth of factual allegations concerning Emory University and its licensing of emtricitabine is perplexing, given that the circumstances surrounding the license were made public years ago. *See* EMORY UNIVERSITY, *Press Release* (July 18, 2005), http://www.emory.edu/news/Releases/ emtri/. Researchers at Emory University developed emtricitabine more than two decades ago. *Id.* In 1996, Emory University licensed the compound to Triangle Pharmaceuticals. *Id.* Seven years later, Defendant Gilead acquired Triangle Pharmaceuticals and subsequently purchased Emory University's royalty interest under the pre-existing license. *Id.* Thus, in 2005, Emory University received an immediate, one-time payment from Gilead and another entity in exchange for relinquishing any rights under its license with Triangle Pharmaceuticals to future royalties based on net sales of emtricitabine products. *Id.* As a result, no direct benefit accrues to Emory University from sales of Genvoya or any other Gilead product that contains emtricitabine.

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by which the persons or entities intended to harm or restrain trade or commerce among the several States, or with foreign nations; (3) which actually injures competition." Kendall v. Visa U.S.A., Inc., 518 F.3d 1042, 1047 (9th Cir. 2008) (citing Les Shockley Racing Inc. v. Nat'l Hot Rod Ass'n, 884 F.2d 504, 507 (9th Cir.1989)). The U.S. Court of Appeals for the Ninth Circuit has explained that the complaint must allege specific times, places, and people relevant to the purported conspiracy, as "a bare allegation of a conspiracy is almost impossible to defend against, particularly where the defendants are large institutions with hundreds of employees entering into contracts and agreements daily." Id. Ultimately, mere conclusions unsupported by factual allegations do not "plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 556 U.S. 662, 664 (2009).

The Complaint contains few references to Emory University. The allegations setting forth the cause of action, most of which are made upon information and belief alone, provide nothing more than conclusory allegations of conspiracy. Plaintiff alleges that "[o]n information and belief, Defendant Emory and Defendant Gilead entered into an exclusive license agreement for patents relating to emtricitabine" and that "Emory has received at least \$525 million in connection with this exclusive license." Compl. ¶ 123. Plaintiff then contends, on information and belief, that Emory University "knew or should have known" that its license was intended to be used in a monopolistic conspiracy." *Id.* ¶ 126. The Complaint contains no allegation or explanation as to how or why a patent license agreement concerning one active ingredient (emtricitabine) would or could give rise to any knowledge at all about other active ingredients, much less knowledge of an alleged monopolistic conspiracy. Based on these conclusory allegations, Plaintiff jumps to the ultimate conclusion, without explanation, that Emory and other entities entered into a conspiracy with Gilead to permit Gilead to maintain monopoly status with respect to sales of tenofovir products, id.  $\P$  127, and that the actions of all defendants are thus unjustified and unlawful, id. ¶¶ 132-33.

The sole factual allegation supporting the plaintiff's hypothetical conspiracy claim against Emory University is the execution of an exclusive licensing agreement with Gilead.

Absent additional factual allegations of misconduct, however, exclusive licenses are not illegal				
under Section 1 of the Sherman Act. See Genentech, Inc. v. Eli Lilly & Co., 998 F.2d 931, 949				
(Fed. Cir. 1993) ("The patenting and licensing of the results of University research is not a				
violation of antitrust principles, and the grant of an exclusive license is a lawful incident of the				
right to exclude provided by the Patent Act Genentech's pleading does not allege more				
substance than the University's grant of an exclusive license to Lilly For these reasons, the				
charge of antitrust violation in the licensing arrangement was correctly dismissed under Rule				
12(b)(6)."), abrogated on other grounds by Wilton v. Seven Falls Co., 515 U.S. 277 (1995); see				
also United States v. Westinghouse Elec. Corp., 648 F.2d 642, 647 (9th Cir. 1981) (declaring that				
the statutory monopoly granted to patentees includes the right to license patents exclusively);				
United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127 (D.C. Cir. 1981) ("A				
patentee may grant one exclusive license or may grant many licenses."). Assuming that Emory				
provides an input to Gilead's product, and that the two organizations are thus in a "vertical"				
relationship, such exclusive licensing agreements "between companies at different levels of the				
distribution chain are presumptively legal under the antitrust laws" absent "exceptional				
circumstances." Spinelli v. Nat'l Football League, 96 F. Supp. 3d 81, 118 (S.D.N.Y. 2015).				
Complaints that fail to allege such circumstances "fail to state a Section 1 claim under the				
Sherman Act and must be dismissed." Id. Plaintiff's Complaint fails to allege facts				
permitting the inference that Emory and Gilead executed the exclusive license as part of an				
unlawful antitrust conspiracy. The plaintiff's statements "on information and belief" concerning				
the existence of a conspiracy are conclusory, rendering Count III legally deficient. See, e.g.,				
Vivendi SA v. T-Mobile USA Inc., 586 F.3d 689, 694 (9th Cir. 2009) (determining that				
allegations based "upon information and belief," and unsupported by further facts, were				
insufficient); Solis v. City of Fresno, No. 1:11-CV-00053, 2012 WL 868681, at *8 (E.D. Cal.				
Mar.13, 2012) ("In the post-Twombly and Iqbal era, pleading on information and belief, without				
more, is insufficient to survive a motion to dismiss for failure to state a claim."). Plaintiff fails to				
allege any facts showing that Emory had any involvement in the development, marketing, sale,				

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or distribution of any TAF-containing product. Plaintiff fails to allege that Emory played any role in the development, marketing, sale, or distribution of Gilead's Genvoya product. Simply put, Plaintiff has not alleged any facts showing that Emory consciously committed to an unlawful scheme with Gilead to restrain trade in a properly defined, relevant market. Emory sole's involvement is the lawful exclusive licensing of emtracitabine to an entity (that was not Gilead at the time) almost twenty years before Gilead released its Genvoya product. This allegation is woefully deficient to state a claim under Section 1 of the Sherman Act. Accordingly, this Court should dismiss Count III as it applies to Emory University.

# B. Emory Specifically Incorporates Gilead's Further Arguments In Support Of Dismissal Of Count III

Emory hereby specifically incorporates the further arguments in support of dismissal of Count III that Gilead has set forth in its motion to dismiss. Those arguments demonstrate the additional legal deficiencies of Plaintiff's Complaint as it relates to the claim against Emory. In particular, Plaintiff lacks antitrust standing to bring its antitrust claim against Emory because Plaintiff is an indirect purchaser of the product at issue. Plaintiff alleges that it purchases Genvoya primarily from Cardinal Health, Compl. ¶ 18, and does not allege that it purchased Genvoya directly from any defendant. As a result, Plaintiff lacks standing under federal antitrust law to bring Count III. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977); *Del. Valley Surgical Supply Inc. v. Johnson & Johnson*, 523 F.3d 1116, 1120-22 (9th Cir. 2008) (recognizing that the "brightline rule" established in *Illinois Brick* has been repeatedly reaffirmed and applied by the United States Supreme Court and the United States Court of Appeals for the Ninth Circuit).

#### IV. CONCLUSION

For the foregoing reasons, and those set forth in Defendant Gilead's motion to dismiss, the Court should dismiss Count III as asserted against Emory University.

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	DEF. EMORY UNIVERSITY'S MOT. TO DISMISS	CASE NO. 3:16-CV-00443-WHA